

Remarks

Reconsideration of this Application is respectfully requested. Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

I. Status of the Claims

Upon entry of the foregoing amendment, claims 31-101 and 154-180 are pending in the application, with claims 31, 49, 68, and 85 being the independent claims. Claims 42-44, 60-62, 79-81, 96-98, and 101 are hereby amended. Claims 102-153 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. New claims 154-180 are sought to be added. These changes are believed to introduce no new matter, and their entry is respectfully requested.

II. The Amendment

Claims have been amended to more particularly point out what Applicants regard as the invention. Claims 42-44, 60-62, 79-81, and 96-98 have been amended to delete the genera *Sporotrichum*, *Myceliophthora*, or *Chaetomium* from the claims and to correct formal matter. Support for the amendment to claims can be found, *inter alia*, at page 4, lines 18-22, and page 9, lines 8-11, of the specification.

Claims 154-177 have been added to recite that the polypeptide having cellulase activity has at least 85%, 90%, or 95% identity to the amino acid sequence set forth in Figure 19 and SEQ ID NO: 31, or has at least 85%, 90%, or 95% identity to amino acids 22-235 of the amino acid sequence set forth in Figure 19 and SEQ ID NO: 31. Support

for the amendment to claims can be found, *inter alia*, at page 11, lines 23-27 of the specification.

New claim 178 recites that the enzyme preparation from claims 31, 49, 68, or 85 further comprises at least one other cellulase of a fungal species belonging to a fungal genus selected from the group consisting of *Melanocarpus* and *Myriococcum*. Support for this claim can be found, *inter alia*, at Examples 3-8 and 13 of the specification. New claims 179-180 recite that the enzyme preparation from claims 31, 49, 68, or 85 is a partially or completely purified *Melanocarpus* cellulase fraction, or a culture supernatant comprising the cellulases derived from *Melanocarpus albomyces*. Support for these claims can be found, *inter alia*, at Examples 9-10 and 13 of the specification.

The amendments to the claims do not introduce any new matter. Accordingly, entry of this amendment is respectfully requested.

III. The Rejection Under 35 U.S.C. § 112, Second Paragraph

At page 2 of the Office action, claims 42-44, 60-62, 79-81, 96-98, 102, 110-115, 123-128, 136-141, and 149-153 have been rejected under 35 U.S.C. § 112, second paragraph, on the ground that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner asserts that these claims are confusing because they "contain genres other than *Melanocarpus*, which is the genus containing SEQ ID NOS: 30 and 31." Applicants respectfully traverse the rejection.

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Solely to expedite prosecution, and not in acquiescence to the Examiner's rejection, Applicants have amended claims 42-44, 60-62, 79-81, and 96-98 to recite *Melanocarpus* and *Myriococcum*, in correspondence with the elected SEQ ID NOS:30 and 31. As discussed in the specification, *Myriococcum* is synonymous with *Melanocarpus*. See page 9, lines 8-11. Claims 102, 110-115, 123-128, 136-141, and 149-153 have been cancelled, thus rendering moot the rejection of these claims.

The Examiner next asserts that claims 44, 62, 81, and 98 are confusing because the preposition, "or," is recited three times in the claims, rather than once. Solely to expedite prosecution and not in acquiescence to the Examiner's rejection, as presently amended, claims 44, 62, 81, and 98 refer only to *Melanocarpus* and *Myriococcum* species. The preposition "or" is only used once in the series.

Finally, the Examiner states that Applicants apparently intended to refer to claim 85, instead of claim 83, in claim 101. Claim 101 has been amended to refer to claim 85, as suggested by the Examiner.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph .

IV. The Rejection Under 35 U.S.C. § 101

Claims 31, 33, 36, 40, 49, 51, 54, 56, 58, 68, 70, 73, 75, 77, 85, 87, 90, 92, and 94 have been rejected under 35 U.S.C. § 101 on the ground that the claimed invention is not supported by either "a specific and substantial asserted utility or a well established utility." The Examiner alleges that the specification "does not teach a utility for a

polypeptide 80% identical with SEQ ID NO:31 or 80% identical with residues 22-235

[of] SEQ ID NO:31." Applicants respectfully traverse the rejection.

The Office has the initial burden of making out a *prima facie* case of lack of utility. To demonstrate a *prima facie* case, the Office must show: "(A) [a]n explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is neither both specific and substantial nor well-established; (B) support for factual findings relied upon in reaching this conclusion; and (C) an evaluation of all relevant evidence of record, including utilities taught in the closest prior art." *See* MPEP Eighth Edition, revised August 2005, § 2107.02 IV. "*Initial Burden is on the Office to Establish a Prima Facie Case and Provide Evidentiary Support Thereof.*" For the following reasons, Applicants submit that a *prima facie* case has not been established.

First, the Examiner did not clearly and properly set forth his reasoning in concluding that a polypeptide with 80% identity to SEQ ID NO:31 or residues 22-235 of SEQ ID NO:31 has no specific and substantial asserted utility or a well established utility. The claimed invention is specifically directed to methods of using a polypeptide or a nucleic acid sequence encoding a polypeptide, having *cellulase activity*. Such invention encompasses the use in these methods of any *equivalent* polypeptide or nucleic acid sequence having 80% identity *and* having cellulase activity. As disclosed in the specification:

[b]y an amino acid sequence that is an "equivalent" of a specific amino acid sequence is meant an amino acid sequence that is not identical to the specific amino acid sequence, but rather contains at least some amino acid changes (deletions, substitutions, inversions, insertions, etc) *that do not essentially affect the biological activity of*

the protein as compared to a similar activity of the specific amino acid sequence, when used for a desired purpose. The biological activity of a cellulase, is its catalytic activity, and/or its ability to bind to cellulosic material . . . Preferably, an "equivalent" amino acid sequence contains at least 80%-99% identity at the amino acid level to the specific amino acid sequence, most preferably at least 90% and in an especially highly preferable embodiment, at least 95% identi[y], at the amino acid level.

page 11, lines 15-27 (emphasis added).

Furthermore,

[t]he invention is intended to be directed to *any* neutral or alkaline cellulase that is a *functional equivalent* of the 20K-cellulase . . . and having one or more of the amino acid sequences described herein, or substantially the same sequence.

page 13, lines 27-30 (emphasis added). Accordingly, the claimed invention is directed to the use of polypeptides that are 80% identical with SEQ ID NO:31 or residues 22-235 of SEQ ID NO:31 and have a similar biological activity of a cellulase, and the specification provides substantial disclosure as to the utility of such polypeptides.

Second, the specification clearly teaches a number of specific and substantial utilities for the claimed polypeptides having cellulase activity, including their use in the textile, detergent, and pulp and paper industries. *See* page 26, line 3 to page 27, line 25, Examples 3-8, and Table VI. Moreover, it has long been known in the art that cellulases have numerous practical uses in the textile, detergent, and other industries. *See id.* pages 1-4. These uses not only have a "real world" use and a well-known utility, but also are specific to the claimed cellulase activity according to the published *Utility Guidelines* and the *MPEP*. *See Revised Interim Utility Guidelines Training Materials*, pages 7-8.

See also MPEP Eighth Edition, revised August 2005, § 2107.01(I). "*Specific and Substantial Requirements.*"

Third, Applicants wish to point out that the present examiner previously allowed claims in a related application directed to polypeptides having 80% identity to SEQ ID NO:31 (Appl. No.: 08/841,636, now U.S. Pat No.: 6,723,549) (Attached as Exhibit A). There is no basis for rejecting these claims now, and they should be allowed for the sake of consistency.

Accordingly, because the claims as amended are limited to a polypeptide that is 80% identical to SEQ ID NO:31 or residues 22-235 of that sequence and which is the *functional equivalent* of these polypeptide sequences with cellulase activity, and because the specification clearly teaches a utility of cellulases of the present invention, there is convincing proof of a specific and substantial asserted utility or a well established utility for a polypeptide that is 80% identical to the claimed sequences and has substantially similar activity. Thus, the Examiner's has not established a *prima facie* showing of lack of utility, and the rejection of claims 31, 33, 36, 40, 49, 51, 54, 56, 58, 68, 70, 73, 75, 77, 85, 87, 90, 92, and 94 under 35 U.S.C. § 101 is improper. Applicants respectfully request reconsideration and withdrawal of the rejection.

V. Rejections Under 35 U.S.C. 112, First Paragraph

A. The Rejection of Claims 31, 33, 36, 40, 49, 51, 54, 56, 58, 68, 70, 73, 75, 77, 85, 87, 90, 92, and 94

At page 3 of the Office action, the Examiner has rejected claims 31, 33, 36, 40, 49, 51, 54, 56, 58, 68, 70, 73, 75, 77, 85, 87, 90, 92, and 94 under 35 U.S.C. § 112, first

paragraph on the ground that the claimed invention is not enabled because it is not supported by either a specific and substantial asserted utility or a well established utility. Applicants respectfully traverse the rejection.

For the reasons stated above in Section IV, Applicants assert that the specification clearly provides an asserted specific and substantial utility for a polypeptide which has similar cellulase activity and is 80% identical with SEQ ID NO:31 or residues 22-235 of that sequence. This is consistent with a well-established utility known in the art. More importantly, one skilled in the art clearly would know how to use such claimed invention. In addition, as mentioned above, the Examiner previously has allowed claims directed to polypeptides having 80% identity to SEQ ID NO:31 in a related application. *See* Exhibit A. In view of the above, it is clear that the claims are enabled. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

***B. The Rejection of Claims 31, 33, 36, 40, 49, 51, 54, 56, 58, 68,
70, 73, 75, 77, 85, 87, 90, 92, and 94***

At page 4 of the Office action, the Examiner has also rejected claims 31, 33, 36, 40, 49, 51, 54, 56, 58, 68, 70, 73, 75, 77, 85, 87, 90, 92, and 94 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner alleges that "the specification does not teach what the characteristics of sequences 80% identical are but rather what the characteristics of sequences that are 100% identical with SEQ ID NO:31 or residues 22-235 of that sequence." Applicants respectfully traverse the rejection.

As stated above on pages 30-33, the specification explicitly teaches that enzymes comprising polypeptides that are 80% identical with SEQ ID NO: 31 or residues 22-235 of that sequence are functional equivalent amino acid sequences of cellulases of SEQ ID NO:31 or residues 22-235 of that sequence. *See* page 11, lines 15-27 and page 13, lines 27-30. Additionally, the specification defines the biological activity of a cellulase as its catalytic activity and/or its ability to bind to cellulosic material. *Id.*, page 11, lines 21-22. Accordingly, the specification clearly identifies the characteristics of a polypeptide sequence that is 80% identical to SEQ ID NO:31 or residues 22-235 of that sequence. Applicants therefore respectfully request reconsideration and withdrawal of the rejection.

C. The Rejection of Claims 102-105, 110-118, 123-131, 136-144, 149-153

At pages 4-5 of the Office action, claims 102-105, 110-118, 123-131, 136-144, and 149-153 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner states that the specification does not teach the use of any and all cellulases from *Melanocarpus*, *Myriococcum*, or *Chaetomium*, but rather specific cellulases from these species, and that the restriction election was only limited to the use of the cellulase of SEQ ID NO: 30 and 31. Applicants respectfully traverse the rejection.

The specification clearly teaches the use of all of the cellulases from *Melanocarpus*, *Myriococcum*, or *Chaetomium*. For instances, Examples 3 and 4 demonstrate that cellulases preparations derived from strain ALKO4237 (*Melanocarpus*) show a good performance in Indigo dye release in neutral conditions. *See* page 32, line 1 to page 35, line 28. Examples 5, 6, and 7 show effectiveness of ALKO4237

(*Melanocarpus*) in biofinishing applications. *See* page 37, line 1 to page 40, line 1.

Example 8 shows effectiveness of neutral cellulase preparations obtained from ALKO4237 (*Melanocarpus*) and ALKO4124 (*Myriococcum*) in denim wash. *See* page 40, line 2 to page 41, line 22. Example 13 shows good stability of neutral cellulase preparations of ALKO4237 (*Melanocarpus*), ALKO4265 (*Chaetomium*), and purified *Melanocarpus* 20K enzyme in detergent solutions. *See* page 55, line 12 to page 57, line 35. Accordingly, the specification discloses the use of cellulases from *Melanocarpus*, *Myriococcum*, or *Chaetomium*, particularly purified 20K preparations, 20K with partially or completely purified *Melanocarpus* cellulase fraction, and culture supernatants (containing essentially all the cellulases) derived from *Melanocarpus albomyces*.

Solely to expedite prosecution, and not in acquiescence to the Examiner's rejection, Applicants have cancelled claims 102-153, thus rendering moot the rejection of these claims. Applicants therefore respectfully request reconsideration and withdrawal of the rejection on these claims.

D. The Rejection of Claims 31, 34, 49, 52, 68, 71, 85, and 88

At page 5 of the Office action, claims 31, 34, 49, 52, 68, 71, 85, and 88 have been rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. The Examiner alleges that it is not clear whether the requirements of 37 CFR 1.801-1.809 as to deposit conditions of DSM 11024 and DSM [11012] and availability upon issuance of a U.S. patent have been met. Applicants respectfully traverse the rejection.

First, Applicants wish to bring the Examiner's attention in the specification regarding the deposit of DSM 11024 and DSM 11012:

Plasmid pALK1221 was deposited as DSM 11024 on June 21, 1996 and λ 4237/5.1 was deposited as DSM 11012 on June 21, 1996, at the Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH, Mascheroder Weg 1B, D-38124 Braunschweig, Germany. Both contain the 20 K-cellulase gene from *Melanocarpus albomyces* CBS 685.95.

Page 9, lines 18-22.

In addition, Applicants submit the following statement:

Statement Regarding the Irrevocable Removal of All Restrictions Imposed by the Depositor on the Availability of the Deposited Biological Material Upon Granting of a Patent

All restrictions imposed by the Depositor on the availability to the public of the deposited biological material in the present application will be irrevocably removed upon the granting of a patent.

Accordingly, all the requirements of 37 CFR 1.801-1.809 as to deposit conditions and availability have been met for the strains DSM 11024 and DSM 11012. Applicants respectfully request reconsideration and withdrawal of the rejection.

V. The Rejection under 35 U.S.C. § 102(b)

At pages 5-6 of the Office action, claims 31, 36, 40-42, 45-49, 54, 58-59, 63-68, 73, 77-78, 82-85, 90, 94-95, and 99-101 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Schulein *et al.* (WO 94/07998) ("the Schulein application") as shown by the Schulein sequence search (ABB04137) ("the A162P cellulase variant"). The Examiner alleges that "the instant reference teaches a method of biostoning, biofinishing, treating wood-derived pulp and improving animal feed using an enzyme

[that] is at least 80% identical with residues 22-235 of SEQ ID NO:31." Applicants respectfully traverse the rejection.

First, the A162P cellulase variant is not 80% identical with residues 22-234 of SEQ ID NO:31 in the claimed invention. Rather, there is at most 78% identity between the two sequences, as indicated by "Best Local similarity". The term "identity" as it is used in the present claims would be understood by one of ordinary skill in the art to mean identical amino acid in both sequences. "Identical" amino acid residues are different from "conservative changes" or "mismatches or gaps." In the sequence search result referenced by the Examiner in the Office action, the identity between the two sequences is indicated in the listing "Best Local Similarity 78.1%," not in the "Query Match." The "Best Local Similarity" is determined by dividing the number of *identical* amino acids by the total number of amino acids in the longer sequence. Such percentage can also be confirmed by manually counting the identical amino acids oneself.

Second, a similar rejection based on the percentage identity between the same claimed sequence (SEQ ID NO:31) and a sequence from a related reference (Schulein *et al.*, US Pat No: 6,001,639) was raised in a related application. *See* Exhibit A. In the Reasons for Allowance Section, the Examiner accepted Applicants' argument, declaration, and exhibit submitted concerning MPSrch that the percentage of identity from Query Match is distinct from percentage of identity from Best Local Similarity. *See* Reasons For Allowance (Attached as Exhibit B). In particular, Query Match includes *both* identical matches as well as conservative matches. Accordingly, Applicants respectfully submit that the A162P cellulase variant is only 78% identical to

residues 22-234 of SEQ ID NO:31, rather than "at least 80%," as alleged by the Examiner in the present claimed invention.

Third, the A162P cellulase variant cannot be considered as an equivalent of the 20K cellulase of residues 22-234 of SEQ ID NO:31 in the present invention. The A162P cellulase variant is a 43 kD endoglucanase taken from *Humicola insolens*. The variant comprises a cellulose binding domain (CBD), a catalytically active domain (CAD), and a linking region joining the CBD and CAD. In contrast, the instant claimed cellulase of SEQ ID NO:31 is a 20K-cellulase taken from *Melanocarpus albomyces* containing only a CAD. The two cellulases are derived from two different genres and therefore two different kinds of cellulase as a result. Furthermore, the comparison between the A162P cellulase variant and the claimed 20 K cellulase was only made at the CAD region. If CBD region of the A162P cellulase variant was taken into account when the comparison was made by the Examiner, the percentage of identity between the two cellulases would have been even lower than 78%.

For all the reasons stated above, Applicants respectfully assert that the A162P cellulase variant from Schulein *et al.* cannot anticipate claims 31, 36, 40-42, 45-49, 54, 58-59, 63-68, 73, 77-78, 82-85, 90, 94-95, and 99-101 of the present invention. Thus, the rejection is improper and should be withdrawn.

Finally, in light of the argument made to claims 31, 49, 68, and 85, and cancellation of claims 105, 118, 131, and 144, Applicants respectfully request reconsideration and withdrawal of objections of dependent claims 32, 35, 37-39, 50, 53, 55, 57, 69, 72, 76, 86, 89, 91, 93, 106, 119, 132, and 145.

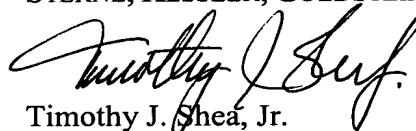
Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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